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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,316	07/17/2003	Robert W. Childers	DI-5766	3437

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EXAMINER	
CHAPMAN, GINGER T	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/623,316	CHILDERS ET AL.	
	Examiner	Art Unit	
	Ginger T. Chapman	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) *27-61* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 April 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

1. Claims 1-61 are pending in the application; claims 27-61 are withdrawn from consideration as being directed to nonelected inventions.

Terminal Disclaimer

2. The terminal disclaimer filed on 27 July 2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US 7,241,272 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

3. Applicant's arguments, see Remarks, filed 27 July 2007, with respect to the rejection(s) of claim 1 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Gura (US 6,960,179 B2).

Claim Rejections - 35 USC § 102

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 1, 2, 4, 6, 7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Gura (US 6,960,179 B2).

6. With respect to claim 1, as seen in Figures 2-4, Gura teaches a system for providing dialysis comprising: a patient fluid loop: Fig. 3: (33, 180) including a first pump (190) (c. 5, l. 44-46) and multiple patient lumens (33, 37); second fluid loop (Fig. 3 (150, 200); Fig 4: 37, 200, 305) including a second pump (fig. 4: 270, 280, 290, 300; c. 5, ll. 49-55) and a medical fluid regenerator (Fig. 2 (40); Fig. 3, (370) and Fig. 8: (370, 414, c. 6, 35-50).

7. As best depicted in Figs. 3 and 8, c. 6, ll. 35-45, Gura teaches a membrane device Fig. 3: (100, 110, 120, 130) in fluid contact with Fig. 8: (140, 415, 370, 360, 465) and separating (420, 430, 440,450, 460) the patient fluid loop Fig. 3. (33, 180) and second fluid loop Fig. 3: (150, 200).

8. With respect to claim 2, Gura teaches the membrane device (30) is a dialyzer.

9. With respect to claim 4, as best depicted in Figure 4, Gura teaches the patient loop is closed (33, 180, 190) except for the transfer of the selected component via the membrane device (30).

10. With respect to claims 6 and 7, Gura teaches urease the medical fluid regenerator includes a uremic toxin sorbent (c. 2, l. 39); includes urease, zirconium phosphate, zirconium oxide, and carbon (c. 2, ll. 39-41).

11. With regard to claim 13, as best depicted in Figure 3, Gura teaches blood is circulated through the patient fluid loop (33, 180) (c. 5, l. 5-6).

12. With respect to claim 14, Gura teaches at least parts of the patient fluid loop and the second fluid loop (sorbent cartridges: 420, 430, 440, 450, 460) are provided in a disposable device (c. 6, ll. 51-65).

13. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Bene et al (US 5,470,483).

14. With respect to claim 3, Gura discloses the claimed invention except for a pressure gradient exists across the membrane device. Pressure gradients and osmotic gradients are conventionally used in dialysis systems to effect transfer of blood impurities across dialyzer membranes. Bene, at c. 3, ll. 13-20, teaches a pressure gradient exists across a dialyzer membrane (3) and thus provides motivation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the dialyzer of Gura/Bizot as taught by Bene since Bene teaches at c. 4, ll. 17-32 that the benefit of forming the system with this design is that it purifies the blood by haemofiltration.

15. Claims 5 and 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Karoor et al (US 7,241,272 B2).

16. With respect to claim 5, Gura discloses the claimed invention except for a nanofilter. Karoor et al, at [0005], provides motivation for a dialysis system that removes toxins from a patient. As seen in Figure 1, Karoor teaches a dialysis system comprising a patient fluid loop (11) and a second fluid loop (12) including a membrane device (20) that includes a filter which allows urea to pass from the patient fluid loop to the second fluid loop [0071] for dialysis thereby the filter of Karoor performs the identical function of allowing urea to pass as the claimed nanofilter. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the dialysis system of Gura comprising a nanofilter as

taught by Karoor in order to provide a dialysis system that removes toxins from the blood of a patient.

17. With regard to claim 8, Gura discloses the claimed invention except for a gas separator that removes gas from the second fluid loop. Karror, at c. 7, ll. 13-19, teaches the ability of a gas separator to remove gases produced during therapy, such as carbon dioxide, and to prevent the gases from being drawn to the sorbent liquid outlet such that the gases can be vented from the system. As seen in Figure 2, Karoor teaches a gas separator (52) that removes gas from a second fluid loop (fig. 2). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Gura including a gas separator as taught by Karoor in order to remove waste byproducts from the system.

18. With regard to claim 9, Gura discloses the claimed invention except for the gas separator (52) and the medical fluid regenerator (32) are provided in a single device. Karoor, in Figure 2, teaches the ability of the gas separator and the medical fluid regenerator to be provided in a single device, thus providing the motivation for such. As seen in Figure 2, Karoor teaches the gas separator (52) and the medical fluid regenerator (32) are provided in a single device [0076]. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to form a gas separator and regenerator in one device since it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art. *Howard v. Detroit Stove Works*, 150 US 164 (1893).

19. With regard to claim 10, Gura discloses the claimed invention except for a gas vent. Karoor, at c. 7, ll. 13-15, teaches the ability of a gas vent to allow gases produced during therapy

to be vented from the system to the environment through a passage, thus providing the motivation for a gas vent. As seen in Figure 2, Karoor teaches a gas vent (54). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Gura with a vent as taught by Karoor since Karoor states, at c. 7, lines 15-20, that the benefit of forming the system with this design is that it restricts gases from being recirculated back into the dialysis fluid, thus eliminating the waste or byproducts from the system.

20. Claim 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Burbank et al (US 2001/0041892 A1).

21. With respect to claim 11, Gura discloses the claimed invention except for a multi-analyte sensor that monitors a concentration of electrolytes in the medical fluid. Burbank, at [0062] teaches the ability of a multi-analyte sensor (100) in a second fluid loop (48) to monitor a concentration of electrolytes in the medical fluid, thus providing motivation. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Gura to include a multi-analyte sensor as taught by Burbank since Burbank states at [0062] that the advantage to forming the system with this design is that if the ionic concentration detected by the sensor falls below a desired range, the sensor detects the drop thereby actuating a controller to adjust the ionic concentration in the second fluid loop thus providing a safer dialysis system.

22. With regard to claim 12, Gura discloses the claimed invention except for peritoneal dialysis fluid is circulated through the patient fluid loop. Burbank, at [0065] teaches the

reprocessing of peritoneal dialysis fluid for reuse in a patient. As seen in Figure 1, Burbank teaches peritoneal dialysis fluid is circulated through the patient fluid loop [0065]. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to circulate the peritoneal dialysis fluid of Burbank through the patient fluid loop of Gura since Gura teaches, at [0065], that the benefit of forming the system with this design is that reconstituted solution can then be collected for reinfusion into the patient's peritoneum for subsequent dialysis.

23. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Geary et al (US 4,950,259).

24. With regard to claim 17, Gura discloses the claimed invention substantially except for a dual lumen catheter. Geary et al, at c. 1, ll. 45-68, provides motivation for a catheter comprising more than a single lumen to increase the efficiency of peritoneal dialysis. As seen in Figures 1-3, Geary et al teach a dual lumen catheter (8) for use with a system for providing dialysis. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the connection of Gura / Bizot comprising a dual lumen catheter as taught by Geary since Geary states at c. 8, ll. 47-60 and c. 9, ll. 10-20 that the advantage of using such a dual lumen catheter is that it maintains a greater solute concentration and osmotic gradient over that of a single lumen catheter and permits continuous flushing thereby providing greater dialysis efficiency.

25. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Bizot et al (US 3,827,975).

26. With respect to claims 18, Gura teaches the claimed invention except for the second fluid loop including an inline fluid heater. Bizot, at c. 4, ll. 15-17, teaches the ability of an inline fluid heater to heat and maintain the dialysis liquid at the desired temperature of between about 37° and 38° C, i.e. to maintain the dialysate at body temperature, thus providing the motivation for a heater in the second fluid loop. As seen in Figure 1, Bizot teaches at least the second fluid loop includes an inline fluid heater (12) (c. 4, ll. 15-17). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the second loop of Gura including an inline fluid heater as taught by Bizot since Bizot states at C. 2, ll. 3-4 and c. 3, ll. 13-20 that the advantage of forming the system with this design is that nitrogen and carbon dioxide, produced as byproducts of the oxidation of urea during dialysis treatment, can be evolved as gases at the temperature of the human body for removal within the system or can be removed by the lungs.

27. With respect to claim 19, Gura/Bizot disclose a heater but do not expressly disclose a radiant heater and a plate heater. Bizot teaches that the heaters and their associated heating function is carried out for the purpose of maintaining the fluid at a proper temperature which prevents undue heating or cooling of the blood to prevent hemolysis. In view of the teachings of Bizot, it would have been obvious to one having ordinary skill in the art at the time the invention was made that the heater disclosed by Bizot is fully capable of comprising either radiant or plate heaters and it appears that any suitable heater may be used for the purpose of maintaining proper temperature; therefore these heaters are equivalent for the desired purpose of maintaining proper

temperature; two equivalents are interchangeable for their desired function, express suggestion of substitution not needed to render such substitution obvious. *In re Siebentritt*, 54 CCPA 1083.

28. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Savitz et al (US 4,229,299).

29. With respect to claim 20, Gura discloses the claimed invention except for a medical fluid sensor that monitors a concentration of electrolytes, e.g. ammonium, in the medical fluid. Savitz, at c. 6, ll. 49-54, provides the motivation for a sensor that monitors a concentration of electrolytes to insure that the dialysate solution has the proper level of salinity and electrolytic characteristics, so that vital components of the blood are not lost to the dialysate solution. As best depicted in Figure 1, Savitz teaches a multi-analyte sensor (105) that monitors a concentration of electrolytes, e.g. ammonium, in the medical fluid. Therefore it would have been obvious to ond having ordinary skill in the art at the time the invention was made to form the system of Gura including a sensor as taught by Savitz since Savitz states, at c. 6, ll. 50-54, that the benefit of forming the system with this design is that it insures that vital components of the blood are not lost to the dialysate solution by ion diffusion across the membrane of the dialyzer, thereby providing a safer dialysis system.

30. Claims 15, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Polaschegg (US 5,522,998).

31. With regard to claim 15, Gura discloses the claimed invention except for a balance chamber. Polaschegg, at c. 2, ll. 3-15, provides motivation for dialysis systems to comprise

balance chambers in order to achieve a steady and constant flow of dialysis fluid. As seen in Figure 1, Polaschegg teaches a dialysis system comprising a patient loop (20) and a second fluid loop (40) and a balance chamber (30) that balances flow within the second fluid loop (40). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Gura including a balance chamber as taught by Polaschegg since Polaschegg states at c. 2, ll. 3-4 and at c. 8, ll. 17, that the benefit of forming the system with this design is that it achieves steady and constant flow of dialysis fluid thereby providing a more efficient dialysis system.

32. With regard to claim 24, Gura discloses the claimed invention except for an ultrafiltrate container in fluid communication with second fluid loop. Polaschegg, at c. 5, ll. 55-60, teaches the ability of an ultrafiltrate container to be located in fluid communication with a second fluid loop, thus providing motivation for such. As seen in Figure 1, Polaschegg discloses an ultrafiltrate container (54) in fluid communication with second fluid loop (40). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Gura having an ultrafiltrate container in fluid communication with the second fluid loop as taught by Polaschegg since Polaschegg states at c. 5, ll. 55-60 that the container can be arranged anywhere between the valves adjacent the balance chamber and it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

33. With regard to claim 25, Gura discloses the claimed invention except for a fluid concentrate container (42) in fluid communication with the second fluid loop. Polaschegg teaches that a fluid concentrate container provides the source of dialysate fluid for the second

fluid loop, thus providing the motivation for the fluid loop to be in fluid communication with source of dialysate which is circulated through the loop. As seen in Figure 1, Polaschegg discloses a fluid concentrate container (42) in fluid communication with the second fluid loop (40). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form fluid concentrate container in fluid communication with the second fluid loop such that dialysate fluid can be supplied through the system.

34. Claims 16, 21-23 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gura in view of Burbank et al (US 6,579,253 B1).

35. With regard to claim 16, Gura discloses the invention substantially as claimed but does not expressly disclose the controller enables fluid flow in opposite directions through the multiple patient lumens. Burbank, at c. 10, ll. 37-38 provides motivation to enable fluid to flow in opposite directions through the patient lumens to rinse back blood to the patient. As seen in Figures 1 and 11, Burbank ('253) teaches a system (fig. 1) for providing dialysis comprising a patient fluid loop (62) and a second fluid loop (68) and controller (22) enabling fluid to flow in opposite directions through the patient lumens (c. 21, ll. 25-38). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made that the controller of Burbank ('892) enable fluid to flow in opposite as taught by Burbank ('253) since Burbank ('253) states at c. 21, ll. 35-38 that the benefit of operating the system in this mode is that it returns fluid to a patient in a bolus volume, e.g. during a hypotensive episode or during rinse back at the end of a dialysis treatment session.

36. With regard to claims 21, 22 and 23, Gura discloses the claimed invention except for a fluid volume sensor in at least one of the patient and second fluid loops; wherein the sensors can be capacitance sensors that use a pump chamber in fluid communication with the loop. Burbank, at c. 23, ll. 35-45, teaches the ability of sensors in fluid communication with the loops to trigger cycles based upon sensed conditions within the loops, thus providing motivation for such. As seen in Figure 11, Burbank discloses a fluid volume sensor (182) in at least one of the patient and second fluid loops (68); the sensors can be, *inter alia*, capacitance sensors (c. 23, ll. 35-40; c. 11, l. 48) that use a pump chamber (214) in fluid communication with the loop (68). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the system of Gura utilizing the sensors as taught by Gura since Gura states at c. 23, ll. 42-43 that the benefit of forming the system with this design is that the sensors can be used to trigger an "end of cycle" signal to switch the valve states within the fluid loops.

37. With regard to claim 26, Gura discloses the claimed invention except for the controller operates the pumps to continuously pump fluid into and out of a patient. Burbank, at c. 7, ll. 5-10, teaches the ability of the system to provide continuous treatment sessions, thus providing the motivation for continuous treatment. Burbank discloses the controller operates the pump (144) continuously to pump fluid into and out of a patient (c. 7, ll. 7-8; c. 21, ll. 3-9). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the controller of Gura to operate the pumps as taught by Burbank to provide continuous treatment thereby providing a more effective dialysis system.

Conclusion

38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

39. Bonomini et al (US 4,269,708) teaches a membrane device in fluid contact with and separating a patient fluid loop and an ultrafiltration loop, and a membrane device that is in fluid contact with an ultrafiltration loop and a third loop including a medical fluid regenerator.

40. Strange et al (US 5,744,042) teaches a membrane device in fluid contact with and separating a patient fluid loop and an ultrafiltration loop, and a membrane device that is in fluid contact with an ultrafiltration loop and a third loop including a medical fluid regenerator.

41. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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